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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,542	07/28/2006	Ooi Kiang Tan	P71388US0	9656

136 7590 05/18/2010

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EXAMINER	
LUM, LEON YUN BON	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
05/18/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,542	TAN ET AL.	
	Examiner	Art Unit	
	Leon Y. Lum	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 March 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,6-10,13-19 and 24-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,6-10,13-19 and 24-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 July 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 6-10, 13-19 and 24-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1 and 15 recite “a planar test surface having a specific affinity" in line 5. It is unclear whether the surface itself has affinity to the analyte or whether it incorporates an element that has affinity to the analyte. The specification only appears to provide support for a surface having molecules thereon that are specific to target analytes, *see* paragraph 0021, but the claim broadly includes a test surface that is itself capable of binding to an analyte through specific affinity or has any configuration that is capable of binding to an analyte through specific affinity. Applicants are requested to clarify this limitation. For prior art purposes, the claim is broadly interpreted to include any configuration, including biomolecules immobilized on nanowires that are capable of binding to an analyte.

Claims 2-3, 6-10, 13-14, 16-19 and 24-28 are vague and indefinite for the same reasons since they are dependent on claim 1 or 15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 6-10, 13, 15-19, 24, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Pat. No. 5,866,321 to Matsue *et al.* ("Matsue") in view of U.S. Pat. No. 7,163,659 to Stasiak *et al*. ("Stasiak") in view of U.S. Pat. No. 5,922,537 to Ewart *et al*. ("Ewart"). Both Stasiak and Ewart are already of record.

i. Claims 1 and 15 are obvious

Matsue describes a biosensor with a reactant immobilized on a first electrode. *See* column 9, line 56 to column 10, line 17; Figure 1A and 1B. The reactant is also exposed to a second electrode such that the reactant is between the first and second electrodes. *Id.* Matsue also describes using the biosensor to detect the presence of an analyte that binds to the reactant, such that binding between the reactant and analyte causes an electrical signal that can be detected. *See* column 7, lines 34-37; column 9, lines 30-42. With this description, Matsue teaches the instant claims except for a ferroelectric transducer.

Ewart describes a method of optimizing a capacitive sensor device by including a dielectric made from ferroelectric ceramic, such as barium titanate. *See* column 14,

lines 10-20.

Stasiak teaches that capacitance detection is useful for obtaining both qualitative and quantitative information. *See* column 12, lines 54-68. Stasiak teaches this type of measurement in the context of a sensor comprising two electrodes, one with a functional layer thereon and the other in contact with a sample such that the sample is between the two electrodes. *See* column 6, lines 52-65; column 12, lines 1-22; and Figure 7. The electrode with the functional layer comprises a dielectric material, *see* column 3, lines 27-29 and column 4, lines 9-12, and can have immobilized biomolecules, such as antibodies, thereon, s*ee* column 8, lines 23-26.

With the foregoing description in mind, one of ordinary skill in the art would have found it obvious to modify Matsue's method by incorporating Ewart's barium titanate as a ferroelectric layer. The combination would therefore produce a sensor by which the reactants are immobilized on the ferroelectric layer. The skilled artisan would have been motivated to make the modification because Ewart indicates that this type of arrangement would optimize capacitance sensing. The skilled artisan would have recognized that capacitance sensing would apply to Matsue's method since Matsue's biosensor can detect any type of electrical measurement, and capacitance sensing is one type of electrical measurement. Moreover, Stasiak indicates that dual-electrode biosensors with reactants in between can be used for capacitance sensing. Since Matsue's biosensor fits this description, the skilled artisan would have found it obvious to apply Ewart's barium titanate ferroelectric layer to Matsue's biosensor. Furthermore, since Ewart describes the ferroelectric layer as applicable in a biosensor, *see* column

14, lines 21-38, the skilled artisan would have had a reasonable expectation of success.

ii. Dependent claims 2 and 3 are obvious

Regarding claims 2 and 3, Stasiak teaches performing parallel tests, one test being a control. *See* column 12, lines 14-22. With this method, a comparison of electrical signals can be performed and the quantity of analyte can be determined. *Id.* It would have been obvious to modify Matsue's method to incorporate Stasiak's comparison test, since doing so would reveal a more accurate determination of analyte quantity. Moreover, regarding claim 3, implicit in this description is the correlation between signal level and analyte concentration.

iii. Dependent claims 6-10, 13, 16-19 and 24 are obvious

Regarding claims 6 and 7, Stasiak teaches the step of applying an electrical current to at least one of the electrodes. *See* column 6, lines 65-66. As would have been apparent to one of ordinary skill in the art, capacitive sensing necessarily involves either applying a current and measuring a change in voltage or applying a voltage and measuring a change in current. Accordingly, it would have been obvious to perform either method using Matsue's method.

Regarding claims 8 and 17, Ewart teaches that the ferroelectric material can be a ferroelectric polymer. *See* column 15, lines 50-51.

Regarding claims 9 and 18, Ewart describes the ferroelectric layer is a thin film. *See* Figure 8.

Regarding claims 10 and 19, Matsue teaches that the analyte can be either an antigen or antibody. *See* column 14, lines 24-30.

Regarding claims 13 and 24, since the reactant is specific for an analyte, the reactant is considered a “probe" molecule. *See supra* rejection of claim 1. Moreover, the reactants are coated onto the biosensor. *See* Figure 1A and 1B.

Regarding claim 16, since the electrodes have stored charge for performing capacitive detection, a voltage source is necessarily provided.

iv. Dependent claims 27 and 28 are obvious

Matsue, Ewart and Stasiak (together “Matsue”) do not teach a thin film that is "about 180 nm thick." However, the skilled artisan would have found it obvious to arrive at this dimension based on the doctrine of routine optimization. In a case decided by the precursor to the Federal Circuit, the Court stated that a claim is not allowable where the skilled artisan could have arrived at the claim through routine experimentation on the optimum or workable ranges of the claim. *In re Aller*, 220 F.2d 454, 456 (CCPA 1955) (stating "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.") In *Aller*, the claims were directed to a process taught by the prior art, except for a specific temperature and acid concentration range. *Id*. The Court, however, held that the claims were not patentable since the skilled artisan could have arrived at the claimed ranges through routine optimization. Similar to the *Aller* case, Matsue teaches all the limitations of claims 27 and 28, except for a size. However, Ewart suggests that a capacitive sensor can be optimized. *See* column 14, lines 10-11. Accordingly, the skilled artisan would have recognized that Matsue’s general conditions could be used as a basis for performing routine experimentation to arrive at an optimal thickness for

the transducer thin film, especially since Ewart indicates that such experimentation is applicable to the thin film.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matsue in view of Ewart and Stasiak as applied to claims 1 and 11-12 above, and further in view of U.S. Pat. No. 4,810,639 to Pankratz.

Matsue, Ewart and Stasiak (together "Matsue"), described above, do not teach the step of "removing a remaining portion of said sample," as claimed.

Pankratz teaches a washing step to remove sample constituents and contaminants not bound to the solid phase. *See* column 8, lines 41-45.

With the foregoing description in mind, one of ordinary skill in the art would have found it obvious to modify Matsue's method by including a washing step to remove unbound analytes, as taught by Pankratz. The skilled artisan would have been motivated to perform the modification based on Pankratz's teaching that the washing step removes contaminants. Indeed, this step would prevent any interference by the contaminants in affecting the assay result. Moreover, Pankratz's washing step is provided in the form of an immunoassay, which is within the scope of Matsue's assay. Accordingly, the skilled artisan would have had a reasonable expectation of success in combining Pankratz's step with Matsue's method.

Claims 25 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsue in view of Ewart and Stasiak as applied to claims 1 and 15 above, and further in view of U.S. Pat. No. 7,527,720 to Ishimaru *et al.* ("Ishimaru").

Matsue, Ewart and Stasiak (together "Matsue") do not teach a movable electrode.

Ishimaru states that where a biosensor is sandwiched by a pair of electrodes, one of the electrodes can be movable in a manner facing the other electrode. *See* column 4, lines 31-39.

With the foregoing description in mind, one of ordinary skill in the art would have found it obvious to modify Matsue's method to include a movable electrode. The movable electrode would be the electrode not attached to the reactant. The skilled artisan would have made the modification because Ishimaru indicates that this technique is well known in the art. Moreover, this would allow the skilled artisan to obtain an optimal signal since the movable electrode could be adjusted appropriately. For the same reason, the skilled artisan would have had a reasonable expectation of success.

Response to Arguments

Applicants' arguments with respect to claims 1 and 15, *see* Response filed March 15, 2010, have been considered but are moot in view of the new ground of rejection. Specifically, Applicants' argument directed at Stasiak's teaching of nanowires is moot since Matsue is now relied upon to teach the claimed planar test surface.

Some of Applicants' arguments, however, merit consideration since they are directed to prior art that are applied above. Applicants argue that Ewart is inapplicable to Stasiak since Ewart discusses the removal of analytes from a test surface. *See* page 9, third paragraph. Although Stasiak is no longer relied upon as the primary reference, this argument is relevant to Matsue. Applicants note that a person of skill in the art would "presumably adopt Ewart's measurement method, which requires removal of the analyte from the test surface." *Id.* This presumption, however, is incorrect. Ewart is relied upon for its teaching that a ferroelectric material would generally benefit capacitance measurements. Such measurements occur whether an analyte is added or removed from an electrode surface. Indeed, both scenarios would cause a change in capacitance, and it is specifically the "change" in capacitance that is measured. *See* Ewart, column 14, lines 10-20; *see also* Stasiak, column 12, lines 44-58. Accordingly, Ewart is applicable to Matsue.

Applicants traverse the rejection of claim 14 based on the same arguments made against claims 1 and 15. However, since these arguments are either moot or not convincing for the foregoing reasons, Applicants' argument against claim 14 is not convincing.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leon Y. Lum whose telephone number is (571) 272-2872. The examiner can normally be reached on Monday to Friday (8:30 am to 5:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark L. Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leon Y. Lum/
Examiner, Art Unit 1641

/Unsu Jung/
Primary Examiner, Art Unit 1641